Participation, Democratic Deficit and Good Regulation: a Case Study of Participatory Strategies in the European Regulation of GMO Products

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A Case Study of Participatory Strategies in the European Regulation of GMO Products

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Contents

Abstract

In the European Union, the institutional reform that risk regulation system has undergone in the last decade has emphasised the need for fostering public participation and stakeholder involvement in decision making processes. Citizen scrutiny, in theory, ought to bring about better governance, and greater participation in public policy decisions is usually regarded as a symptom of a healthy democracy. By presenting evidence from two case studies in the field of biotechnology regulation, this paper aims to prove that taking participation as a *tout court* advantage is a mistake.

1. Introduction

In recent years there has been a renewed interest in the participation of lay-people in procedures of risk-management. The debate peaked in the 1980's with the anti-nuclear movement, and again more recently as a reaction to the food scandals of the mid 1990's. In the wake of the BSE crisis, there has been a proliferation of Community rules on the production, processing and retailing of food products, along with an augmentation of scientific committees in order to cope with increased regulatory demand. Parallel to the increase in regulatory density, a number of normative questions has been raised. One of the most persistently raised questions is what place, if any, should lay people and their opinions be given in the processes of risk government. This issue is often put in terms of 'democratisation of risk', which leads to the claim that lay people ought to have input in two areas : firstly, in the risks they are willing to take, and secondly, in the regulatory procedures available to reduce such risks. Moreover, issues regarding risk mitigation and distribution across the population should be subject to democratic assessment.

Despite the fact that much has been written on the *pros* and *cons* of strengthening democratic participation in institutions for risk regulation, there seems to be little clarity on what ought to be the objectives of increased participation. This paper argues that, in the literature, the demand for democratisation of risk regulation procedures often conflates two distinct, although correlated, claims:

> *i) Participatory claim:* Broadening participation enhances democratic legitimacy, as it is an expression of self-governance. Risk is being imposed, through regulation, on people who have not consented to it. Public participation in decision making concerning risk, as well as the openness and transparency of the procedures of risk assessment and management, are

fundamental preconditions for granting democratic *legitimacy* to regulating bodies, insofar as they can exercise control on the decision makers, and themselves be part of the decision making process.

ii) Epistemic claim: The inclusion of lay people in policy-making will lead to better output. Risk assessment is not a value-free enterprise, but presupposes value judgments. Deciding, for example, which risk to prioritise in assessment procedures, or how to gather and interpret data depends upon the values attributed to the various options at stake. In order to appropriately interpret and understand these values lay people, as well as experts from outside the government, must be consulted. In this context the following question arises: are the outcomes of decision making about risk *justified* rules (e.g. rules that appropriately mitigate the effects of risk, fairly distribute risk etc.)?

Because there exists in the current literature a flourishing of interpretations of the meaning of legitimation and justification, and of their relations, in this essay I apply a distinction that is often used in contemporary political studies. Charles Taylor has described legitimacy as a function of the allegiance, loyalty, or identification of the citizens with the rulers and the rules of a given political community (Taylor, 1985). Thus legitimation speaks of the relations between the state authority and its subjects (Simmons, 1999). For this reason, when we talk about a 'democratic deficit' we refer to a lack of trust in public authorities and their representatives. Transparency, accountability and improved participation may remedy this.

Justification, instead, concerns rules and the reasons that stand behind them. It is not a matter of allegiance, rather the acknowledgment of such reasons that inform decisions by those affected by them. Such a consensus has been understood either as *rational* (agreement under ideal conditions *per* Habermas) or based on participation and *actual assent* (D'Agostino, 1996).

When citizens can see that they are ruled by good (i.e., justified) laws, their relationship with those responsible for the making of those laws improves, and – arguably – legitimacy is thereby fostered. Yet the question of whether risk regulation will improve through lay participation may have two very different answers, depending on whether we refer to participatory or epistemic claims. Moreover, whether these practices can be a remedy to the democratic deficit, or rather improve the grounds (argument, methodology, evidence used etc.) on which public decisions rest, is a question of whether they address justification or legitimating problems.

Although various authors have identified a plurality of tasks that are assigned to participatory practices (Shrader Frechette, 1991; Hood *et al*., 2000), many influential theorists insist that the two claims are interlinked rather than

distinct, and that they are two sides of the same coin. According to these authors, through sustained effort to make well-informed decisions based on balanced and competing arguments in which the public is involved, people are capable of recognising the reasons that support decision making outcomes, may form and reform their preferences, and thereby reduce the possibility of dissent (Fishkin, 2005). Supporters of deliberative democracy have established a strong link between the two claims, understanding the epistemic aim of democratic practices as not confined to the production of knowledge, but rather as also including the fostering of mutual understanding and the improvement of social interaction (Levison, 1992).

However, I argue that keeping a distinction between participatory and epistemic claims, can foster a better understanding as to what we expect from democratic procedures and it clears the way for critical analysis of the procedures actually in place, and the identification of indicators for their evaluation. Both strengthening the legitimation of public institutions and improving justification of decision outcomes are important democratic goals, which may require public participation and involvement (hereinafter "democratic practices"). However, there are several models of these practices that are embodied in our institutions, and an evaluation of their relative merits will help us to choose the most effective.

The context, the subject matter and, particularly, the goals that we set for our institutions determine what democratic practices we can best apply. Moreover, the implementation of democratic practices is a matter of degree or extent, and requires, *inter alia*, costs in terms of public resources, time, and arguably, efficiency. By clarifying what we want from them, we will be in a better position to determine what is worth our while.

The following section considers each claim and explains their standing in this debate. Sections 3, 4 and 5 clarify the necessity of the distinction that I propose by discussing some examples in the field of risk regulation concerning novel biotechnologies in the European Union. The final section explains what bearing the distinction has on the way we think of justification and legitimacy of public regulation.

2. Two different ideas of 'democratic' practices

Initiatives for strengthening democratic participation are almost invariably looked upon with a favourable eye by practitioners (especially NGO's and consumer associations), but also by many theorists (Hunold and Young, 1998). Yet, when moving from theory to practice, what purpose do these initiatives serve? I believe that the examination of the purposes of these practices is the

first necessary step to evaluating them. Although there may be a multiplicity of tasks implied in any initiative for lay involvement in decision making processes (and also for fostering openness, transparency and accountability), the two main motivations that I identify are those of *enhancing legitimation* and *improving justification*.

a) Participatory claim

The first claim, which I have referred to as the '*participatory claim',* is the less specific of the two. Contemporary political theory has devoted great effort to advocating greater involvement of citizens in governance and participation in different areas of life within the community, and has argued that this contributes to the democratic *legitimacy* of public institutions (Hood *et al*., 2003). Citizens should be in a position to participate in decisions that affect them, and that have an important impact on their lives. Industrial societies are often regarded as deficient in this respect.

In his description of industrial modernity as the age of 'risk society' Ulrich Beck identifies a 'truncated democracy` in which democratic processes and political decision-making have surrendered to the dynamics of technological change. However, the risks and benefits inherent in technological applications and scientific innovation still affect every citizen, and it is a core democratic principle that all those affected by a certain decision ought to have levers of influence on the decision making process. In order to reclaim democratic control over scientific and technological progress, Beck calls for increased openness towards the public, democratic accountability and participation in risk assessment and risk management (Beck, 1999).

In the same vein, several scholars and practitioners contend that public control over government-mandated regulatory activities is a means of remedy for the lack of transparent regulatory appraisal that can evenly represent all social parties (Fiorino, 1989; Perhac, 1998, Munton, 2003).

The reason why the problem of regulating risk has attracted such great attention is that it represents a nodal point for exploring the tensions between the need to address technical difficulties, which seems to require experts, and the democratic commitment to find public rules and processes that are transparent and open to citizens for appraisal and scrutiny. The concern is that scientists may decide on policy issues, by disguising their power under technical decision making (Jasanoff, 1987: 225).

In particular, advocates of a more democratic process of risk assessment see the current procedures as biased towards market interests (James *et al.,* 1999: 14; Hood *et al*., 2003: 100). In Europe, the BSE scandal has become the sym-

bol of the failure of politics to take responsibility over regulatory issues, and ensure effective risk governance (Medina, 1997). The suspicion that the judgment of the appointed experts served the interests of the meat industry, rather than those of consumers, has been used as evidence that science was biased, not very transparent and therefore a legitimate object of scepticism. As a means of remedy, the Commission's *White Paper on Food Safety* (2000) states the intention to "promote dialogue with consumers to encourage their involvement in food safety policy" (12). The commitment to a greater civic participation, transparency and openness was put forward as a way to give consumer interests a new centrality (Vogel, 2001: 16).

Citizens, it is argued, are disenchanted and reclaim transparency in decision making, greater accountability of appointed experts, but also express a concern for the selection process of these experts, and the possible conflict of interests that may thus arise. For example, it is often contested that several of the appointed experts had previously worked for companies that have direct stakes in regulatory outcomes (Hood *et al*., 2003: 112-132).

For these reasons, practices designed to enhance transparency, openness, accountability and the independence of the regulative processes are increasing in popularity[1], and are normally considered a step towards more democratic institutions. These practices, arguably, bring citizens close to the institutions, and empower the consumers who would otherwise be at risk of domination by the other stakeholders, such as the industry. To what extent these goals can be met will be the object of the discussion in the following sections.

b) Epistemic claim

The claim that I have referred to as '*epistemic'* is stronger and more specific than the generic claim that public processes and institutions should be an expression of self-governance. Instead, it pertains to the nature of risk assessment itself: from the organisation of risk assessment we move to the substantive question of how we should assess risk and whether the public should participate in the assessment. In order to have *justified* rules we need to have good rules, and some authors hold that lay people can contribute to produce better regulation by bringing to the decision making process experiences, reasons and perspectives that experts would not otherwise consider (Wynne, 1987).

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1 Falke (2002) has shown that commitments to openness and transparency, accountability, responsibility and independence are shared by several food regulation authorities (he considers the UK, Canada, The Netherlands, France, US and Germany).

According to the traditional positivist approach, it is possible to give an objective measure of risk, and to exclude all normative elements, so that risk evaluation is an enterprise that can appropriately be left to experts and scientists (Lowarance, 1976). In the last decades, the critics of this approach have outnumbered its supporters, and the role of evaluative judgments has been taken into serious consideration. "Hazards", it has been argued, "are threats to people and what they value as risk are the measurement of the hazards" (Kates and Kasperson, 1983). Risk assessment implies a judgment of what risks are acceptable, or negligible. Yet the thresholds of acceptability or negligibility are not absolute. Sociological reserach has shown, for example, that people tend to consider risky situations that are unfamiliar and where new technologies are involved as less acceptable (Lash, 2000). As such, risk assessment cannot be a value-free enterprise, but we need judgments on which risks should be subject to assessment, on the methodology in place and on how various possible outcomes should be evaluated (Thompson and Dean, 1996). For this reason, the role of scientific expertise should be sized down to leave more room to the lay public, and let people express what is a risk to them, abandoning the dualism between 'perceived risk ' and 'real risk'.

This approach has the indubitable merit of pointing to the fact that methodological choices and debates on which kind of risk should be subject to regulative procedure are a matter of high relevance, which should not be reduced to a technical matter or subtracted to the political sphere. Yet it seems unfair to state, as Slovic (2003), for one, does, that at present there is little scientific awareness of the coexistence of many alternative methods for the calculation of probability. Methodological conflicts among risk assessors about the best indicators for the assessment of the probability (or the criteria for choosing a theory of probability against another) for gathering and interpreting data, ranking competing kinds of risk involved in a same course of action under conditions of great uncertainty are very well known and debated and are part of a wider debate over the validity of scientific knowledge (Shrader Frechette, 1991; Lucas, 2002; Hansson, 1996). As Giddens observes: "Characteristics of the new situation is that the experts disagree with each other. Rather than there being a clear-cut set of findings to turn to for policy-makers, research generates ambiguous conclusions and disputed interpretations" (1998: 59).

The core of the epistemic question is not whether there is or there is not a plurality of technical methodologies, but rather how we can go from that plurality to a collective action (i.e. the choice of regulatory procedure), and whether strategies for public involvement effectively improve the decision making process from an epistemic perspective. The claim that there is no value-free conception of risk should not lead us to conclude that 'anything goes', otherwise we would have to also accept that risk and risk regulation can

only be imposed, but not justified. In other words, we would not be able to say that one regulatory framework is preferable to another. Instead, the evaluative aspects of risk regulation point to the fact that decisions involve judgments of justice.

According to some, the appropriate methodologies should include some strategies for public involvement. This is part of the more general idea that the exchange of information and views, as well as the processes of self-reflection have a positive impact on decision outcomes. Some authors (Majone, 1989; Wynne and Irwin, 1996) have suggested that the epistemic aspect of participation has to do with the necessity to include information and insight coming from *experts* outside the government appointed committee and agencies, so as to improve the epistemic outcome of decision making (e.g. to make more accurate prediction of risk, or to manage it more efficiently).[2] The outcome of decision making must be vindicated and justified as epistemically sound before a wider community. Stakeholders can challenge decisions, not only with evidence-based material, but also with objections founded in value considerations, against which decisions makers have to defend their positions. Including *lay people* in the decision process is thought of as adding another perspective to the issues at stake (Wynne 1987). This, arguably, aims at delivering rationally acceptable results (Habermas, 1990; Gutmann and Thompson, 1996), and improving the epistemic quality of the process.

In summary, the second claim is that in order to have valid tools for decision making, risk-assessment needs to be practiced not only in a transparent and open manner by using the most up to date scientific knowledge and experience, but it also requires a democratic involvement in order to make possible impartial decisions on what can be the principled choices for specific kinds of risk. To what extent such an involvement can effectively serve the democratic ideal of justification remains to be discussed.

The thesis that I put forward in the remainder of this paper is that, although we should be concerned both with the *legitimacy* of our democratic institutions and with the *justification* of the substantial rules and decisions that are generated by those institution, it would be a mistake to take legitimacy and justification as one problem that requires one single solution. There is a plurality of models available for structuring public participation and involvement into in-

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2 Rothstein (2004) opposes this epistemic aspect to a 'normative' aspect of participation, which on his account reflects the fact that risk assessment has to do with value judgments and therefore is not value-free. I think that such a distinction fails to capture the normative aspects involved in many decisions (such as methodological choices) that are apparently of an epistemic nature.

stitutional regulatory practices, and only by clarifying what we expect from these practices we will be able to decide which are the most appropriate and effective in enhancing our goals.

3. Risk assessment in the EU: the case of EFSA

In order to illustrate my point, I propose looking to the EFSA (European Food Safety Authority), and to the scientific panel on genetically modified organisms (GMO Panel), which is the body within the EFSA that deals with novel biotechnologies – perhaps the most debated risk issue in recent years.

The EFSA was instituted with European Parliament and Council Regulation 178/2002/EC of 28 January 2002 (laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety) as a response to the food scandals and international trade disputes of the 1990's, and the subsequent accusations of a mismanagement of risk at European level.

In particular, concerning genetically modified products, critics of the European regulatory approach, especially from the other side of the Atlantic, see the issue as highly politicised and as giving too much weigh to 'passions' and 'fears' rather than 'sound science' with public and non-governmental organisations playing a very influential role (Vogel, 2001, 4). On the other hand, European public opinion, and especially environmentalist NGO's, criticise the marginal role given to consumers and their opinions at institutional level.

The institution of the EFSA as an independent scientific agency was intended to meet the demand for sound and independent scientific advice with the task of risk assessment, whilst the task of risk management, which explicitly involves political choices, was left to the national authorities and the European Commission (Lafond, 2001). The EFSA's competences encompass all matters linked to food and feed safety including animal health and welfare, plant protection, nutrition and risk communication. The EFSA has no regulatory competences of its own, but deals principally with requests for risk assessments from the European Commission, and its mandate includes promoting studies and research on safety issues of its own initiative, collecting and analysing scientific data and offering support to the Commission in case of a food crisis. Moreover it can communicate directly with the public.

EFSA's GMO Panel

The EFSA's Scientific GMO Panel deals with questions of genetically modified organisms as defined in Directive 2001/18/EC (regulating a deliberate release into the environment of GMO's) and 2003/1829/EC (regulating GM food and feed). In particular, it plays an important role in the procedures for authorisation of GMO's and has the task of expressing opinions on the deliberate release into the environment, and the marketing of genetically modified food and feed, which includes their derived products. The two directives set two different (although similar) procedures for authorisation.

For authorisations under Directive 2001/18/EC (deliberate release into the environment), companies send a dossier application to a national authority, which will lead the assessment procedure. The competent authority notifies the application to the Commission and the Member States and a summary notification (SNIF) is made available to the public. After evaluating the dossier the competent authority publishes an assessment report. Within 30 days of publication of both the summary notification and of the assessment report, the general public is invited to send comments, via a website (http://gmoinfo.jrc.it, hereinafter *Gmoinfo*) provided by the Joint Research Centre of the Commission (based in Ispra, Italy) with the support of DG Environment. It must be noted that the aim of the website is to inform the public, and to manage the information flow concerning specific assessment reports between the competent agencies and the public. EC legislation rules that public comments should be taken in 'due consideration' by the competent authority. However, the form due consideration should take is entirely left to the national authority initiative (for further discussion see Ferretti, 2006).

In case other Member States advance objections to the opinion of the authority leading the notification, a procedure of conciliation is initiated, with the aim of arriving at a consensual decision. If divergences persist, the dossier application is then passed on to the EFSA, which carries out a risk assessment on the basis of the notification dossier. Once the EFSA issues an opinion, the Commission prepares a draft decision to be submitted to the Regulatory Committee in Brussels. The Regulatory Committee is comprised of representatives of national governments, which through qualified majority vote can accept or reject the proposal of the Commission. When the Committee expresses a favourable opinion, the Commission shall adopt the decision. In case the measures envisaged are not in accordance with the opinion of the Committee, or no opinion is delivered, the Commission submits its proposal to the Council of Ministers for approval (or rejection) under qualified majority voting. If on the expiring of three months no majority vote is obtained in favour of or against

the authorisation, the proposed legal act shall be adopted by the Commission (Directive 2003/1829).

The procedure in place for authorisation under 2003/1829/EC (food and feed) gives a more central role to the EFSA, which is in charge of risk assessment. Companies apply by sending a dossier application (or notification) to a national authority, which then refers the application to the EFSA. The application is made available to the other Member States and the Commission, and a summary of the application dossier is also published on the EFSA's website. After evaluating the application documents and requesting further information when necessary, the EFSA publishes an opinion. Based on this opinion the Commission shall adopt a decision, having once submitted it for approval to the Standing Committee on Food Chain and Animal Health (chaired by DG SANCO) comprised of representatives of the Member States. Also, in such a case, the public can make comments to the Commission on the overall final opinion expressed by the EFSA on a web page made available by the GM Food and Feed Unit (DG SANCO). In this case all comments are published on the same webpage, and the Commission is committed to give to the comments 'due consideration', but also to make comments available to the competent national authorities that can take them into consideration in their review of the application.

In accepting (or rejecting) authorisations, the Commission has to take into account the EFSA's opinion and justify any decision that diverges from the line of action suggested by the EFSA.

In the next two sections, I shall discuss two cases of procedures for authorisation that I believe are useful in exploring the potentialities and limitations of the participatory practices in place within this context.

4. Participatory claim: MON 863

Participation is considered by some (Benhabib, 1996; Fishkin, 2005) as a remedy to the hegemony that some groups entertain in the decision making process. In this sense, promoting participation means redressing the structural inequalities inscribed in the decision making process. In particular, it is within the remit of the EFSA to give to consumers their due place so that they can defend their interests. As explained in *section 2*, in the case of food safety, the objective of counterbalancing the interests of science by giving more space to the consumer was one of the highlights of the *White Paper on Food Safety* (2000), which corresponds to what I called a "participatory claim". Are the institutional mechanisms for the participation of the public in the authorization process of GMO products an efficient means to this end?

Procedures for authorisation include a model of participation that is to give 'due consideration' to the arguments of all relevant stakeholders.[3] When an application dossier is notified to the competent authority, all interested parties are invited to contribute facts and evidence in order to express their opinion on the submitted document and, when they judge it opportune, to rebut the arguments presented by the applicant on the basis of fact, evidence and argument. The competent authority should act as a neutral arbiter between the parties, appraise the evidence and arguments brought to the decision table and pronounce a verdict. In this system it is not expected, as in many deliberative practices, that actors change their preferences through information, dialogue and mutual learning (Elster, 1998; Fishkin, 1991), but instead everyone defends their own case, and the verdict establishes winners and losers, without space for mediation and conciliation (McGarity, 1990; Ferretti, 2006). The underlying principle is that the best argument wins, and the competent agency decides what counts as the best argument, by following the basic rules of logic, but also the guidelines established to advise the process such as the legal framework, or in this specific case, the agreed guidelines for risk assessment.

In this model, the agenda is shaped by those who prepare the document/proposal to be submitted for appraisal to the interested parties. In the case of application for authorisation, the dossier, although following a standard format requested by the Community, is produced by the applicant company. The rationale is to ensure ex-ante accountability and to put the strains of justification on the applicant. However, this also puts the company in an advantageous position compared to the parties, as the quality and organisation of the information submitted to the competent authorities are selected by the applicant. Although the EFSA and the national authorities are in a position to request additional information on the application dossier, or to object to the information provided, time limits and the right to commercial secrecy often prevent a thorough investigation of possible elements against a positive result of the application.

Data contained in dossier applications is based on studies commissioned by the applicant company, even if it often rely upon information produced by third parties on the company's request. Paradoxically, the applicant companies are in the best position to put their products to test. This is primarily because they can attract scientists of excellence and employ vast resources. Additional-

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3 McGarity (1990) in his taxonomy of participatory practices identifies six public participation models: the exclusionary model; the confrontational model, the adversarial model; the due consideration model; the mediation model; and the advisory committee model.

ly, being in charge of the presentation of data and materials, the company can conceal unfavourable evidence and information. Although the EFSA can decide to conduct tests on the product, it relies predominantly on the applicant's source of information. Consequently, the influence of the company on the issues to be discussed is conspicuous. I shall argue that such an institutional architecture leaves lay people in a situation of structural inequality, especially in comparison to the applicant company.

The case of pesticide resistant maize MON 863 is instructive in this sense. Put briefly, in the summer 2002 Monsanto submitted an application for the registration of genetically modified MON 863 to the competent German authorities. MON 863 is a variant of maize (Zea mays), genetically modified in order to produce pesticide, and in particular the toxin CryBb1. Being different from toxins produced by other GMO products previously evaluated by EC authorities, it begs special attention due to its toxicological characteristics. The application dossier included a 90 days sub-chronic study on rodents, prepared by a third party and commissioned by Monsanto, subsequently updated to fulfil the requirements of the European authorities.[4]

As part of Member States' review of the dossier assessment, some national authorities requested further information on the results of the study, which was provided by the applicant by issuing some new data analysis and evaluations of the rodent-based testing.[5] Given the discordant evaluations of the competent national authorities, the EFSA was required to express an opinion, which was issued in April 2004, concluding that on the basis of the documents acquired, the product is unlikely to cause adverse effects on human and animal health or on the environment, and that the information provided by the applicant satisfactorily addressed the outstanding questions of the national authorities.

In September 2004 the Regulatory Committee discussed a draft of the Commission decision to authorise the placement of the GM maize on the market. Due to a new evaluation of the rat study by German authorities, already reviewed by the EFSA Panel, the European Commission decided to postpone a vote on MON 863 maize, and the EFSA was asked to reconsider the case of

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4 13 week Dietary Subchronic Comparison Study with MON 863 Corn in Rats Preceded by a 1 – Week Baseline Food Consumption Determination with PMI Certified Rodent Diet #5002. (OECD Protocol 408), Covance Study No. 6l03-293, issued 17th December 2002.

5 Retrospective Evaluation of Renal Tissues and data from Monsanto Co. Study CV – 2000 – 260 (MSL 18175): a 13 week Rat Feeding Study with MON 863 Corn, (Covance Laboratories Study No 6103-293); Supplemental Analysis of Selected Findings on the Rat 90-day Feeding Study with MON 863 Maize, Report MSL – 18175; Hammond, B.G. and Ward, D.P., Monsanto Co., USA, 24th May 2004.

MON 863 in the light of this new evaluation. The subject of the disagreement was the statistical relevance of some of the rat study results. After scientific revaluation the EFSA concluded that the new evidence provided did not change the assessment outcomes, and in October 2004 the EFSA reaffirmed its opinion, according to which there is no concern about the safety of the product, and on the quality of its nutritional properties.

The representatives of the Member States in the Regulatory Committee could not reach a qualified voting decision on MON 863, and thus the Commission submitted its proposal to the Council. Since on the expiring of the period laid down by Art. 30 (2) of Directive 2001/18/EC the Council had neither adopted the proposed measures nor indicated its opposition to them, the Commission on 8 August 2005 adopted the Decision 2005/608/CE favourable to the placing on the market of MON 863. Some independent experts are however currently processing the data made available by Monsanto so as to prove the inadequacy of the statistical interpretations provided and accepted by the EFSA (see for example Seralini, 2005).

While the Member States were called to express an opinion on the case, in the Spring of 2005 the attention of the public was newly drawn by the media to some statistical results of Monsanto's rat study, from which allegedly significant differences emerge between control rats and treated rats. The British newspaper *The Independent* revealed that a Monsanto's internal scientific report at the US-based company contained data on kidney malformations and damages to the immune system observed in rats fed with the crop. A massive mobilisation of public opinion and environmentalist NGO's followed.

Monsanto's representatives replied that the differences revealed by the study are not statistically significant, and in response to public concerns, stated that MON 863 is not a new product, and that there is no record of health problems associated with the product's consumption. Moreover, they stated that the product has already been approved as equally safe as conventional maize by various food authorities in the world, including the U.S. and Canada.

The debate about the safety of MON 863 was exacerbated by Monsanto's refusal to make public the study results in full, on grounds of commercial secrecy. Under pressure from environmentalist NGO's, lead by Greenpeace, the German authorities compelled Monsanto to make the document available on the basis of Art. 25 of Directive 2001/18/EC, according to which risk assessment in environmental and health matters should be open to public scrutiny. Monsanto appealed against the decision to disclose the document, but in June 2005 the higher administrative court in Münster ordered the study to be released.

This case invites important reflections on the role that the applicant companies play in the authorisation process, and their power position in relation to

other interested parties. The evidence produced by the applicant, and in particular the aforementioned rat study, was effectively submitted to the scrutiny of the interested parties. The competent authorities were able to ask for further information and evidence to be considered in the authorisation process. However, the applicant was given the prerogative of publishing selected findings only, protected by the principle of commercial secrecy. Greenpeace, which led the public campaign for transparency, objected in its reports on MON 863 (see, for example, Seralini, 2005) that the publication of selected data only ran against the public interest. Thus, the publication of the summary application and assessment report makes decision makers more accountable to the public, as they have to justify their evaluations of the case. Yet, when moving from the matter of transparency to the most pressing problem of whether the study results actually provided evidence of the safety of the product, Greenpeace itself had only Monsanto's study to rely on.

From this, it emerges that in order to redress the imbalance of power among different stakeholder groups it is not enough to grant public participation, but asymmetries in information should be targeted. Corporate dominance is one of the factors that most contributes to the negative attitude that Europeans have towards novel biotechnologies (Bernauer, 2003). The dominance of multinationals derives not from a privileged access to the decision making process, but from the role the industry plays in the production and management of the information. Public participation strategies can hardly break such dominance. The method of 'due consideration' offers lay people the possibility to participate. It also creates the impression that all interested parties are given a fair chance in the decision making process, but it is hardly possible that lay people can give a contribution that is as weighty as that of the applicant company which largely leads the whole process. Thus, people are shown that they could take part in the decisional process, but also that the case is 'won' by other actors that can produce better arguments and evidence. The authority can claim *legitimacy* for its decisions (which is ultimately a political one), as the process has included all stakeholders, even if, in fact, the applicant company predominates in the process that leads to a scientific opinion on authorisation, and the procedures for public participation in place are not effective in breaking such dominance, which is inscribed in the institutional design itself.

5. Epistemic claim: Florigene Moonlight

From the epistemic point of view, supporters of democratic practices hold that lay people can proficiently contribute with their view, ideas, information and evidence to improve the outcome of the decision making.

In the case of procedures for authorisation for the marketing of GMO products, the comments of the public are invited through the already mentioned *Gmoinfo* website and electronically recorded. I propose to look into comments regarding a particular summary notification (SNIF) and the assessment report produced by the competent authority. This allows us the opportunity to observe the mechanism of due consideration in greater detail. Since most national authorities simply do not include any section on public comments in their assessment report, I have selected one case, Florigene Moonlight (C/NL/04/02), where public comments are summarised and addressed. A further reason for selecting this case is that the entire body of comments was made available to me by DG Environment. From an in-depth qualitative analysis of these comments and the relative answers provided by the competent authority, it is possible to probe into the adequacy of this institutional mechanism of participation in order to inform the decision making process by means of insights coming from laypeople. In other words, it is possible to assess to what extent they can contribute to better decision, from an epistemic point of view.

In September 2004, Florigene Limited (Australia) applied under Directive 2001/18/EC to the competent authority of the Netherlands (Dutch Scientific Advisory Committee, or COGEM) for the import and marketing Florigene Moonlight carnations. This carnation variety has a modified flower colour and contains an herbicide-resistant gene. The scope of the notification did not include authorisation for consumption or cultivation, and the product was intended for ornamental use only. The competent Dutch authority (COGEM) judged all risks to the environment or human health to be negligible.

Six comments on the summary notification were sent from four different member states (Belgium, Italy, the Netherlands, and the UK). In its assessment report, COGEM only addresses the three comments originating from the Netherlands, and specifies that other comments should be addressed by the other Member States' competent authorities during their national assessment. This is however an interpretation of the directive which is not based on any official document. The directive does not specify the competent authority that should give 'due consideration'. The procedure, according to which Member States, should take into consideration the comments issued by their nationals, developed from the practical need of avoiding language barriers, even though most comments are issued in English. In fact, there is no evidence to suggest that the competent authorities of the interested Member States actually addressed comments from their nationals, nor are they required to produce evidence that they have taken comments into consideration (Consiglio dei Diritti Genetici, 2005).

The three 'Dutch' comments for which COGEM takes responsibility, are addressed in the assessment report, and are dismissed on the basis that the objec-

tions raised go beyond the scope of Directive 2001/18/EC. However it is interesting, I believe, to take a closer look to the concerns expressed by consumers.

Two of the comments concern whether it was worth running any risk in order to have, say, carnations of a different colour. In the words of one of the people who commented on SNIF C/NL/04/02: "*Are you crazy? As if nature is not beautiful enough*". Another comment, sent after the publication of the assessment report asked, rhetorically, whether there were no more urgent tasks that scientist should address other than modifying flower colour. Although these comments are dismissed as 'ideological' in the reply provided by COGEM, it seems plausible to interpret them as expressing an evaluation of risk versus benefits, and conclude that even the minimum risk is not worth taking in order to have carnations of a different colour. And who can we deem as foolish for thinking so?

In the same vein, someone else suggested that GM products should only be used in cases of necessity, there being no available alternatives, and "*modification of flower colour is not a legitimate ground*". It is a request on good grounds to justify that GMO's are needed, which can be easily read as a criticism to the principle of substantial equivalence that "embodies the concept that if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety (i.e., the food or food component can be concluded to be as safe as the conventional food or food component)" (FAO/WTO, 1996: 4). This principle has been the object of various scientific controversies, pointing mainly to the absence of an appropriate definition of the concept of equivalence (Millstone *et al*., 1999).

The Competent Agency of the Netherlands is correct in asserting that all these concerns fall outside the standards set by Directive 2001/18/EC. However these restrictions imposed by legislation raise doubts about the capacity of the participation mechanism to capture what people take to be a risk, and the relevant considerations in its regulation. In fact, there is no institutionalised procedure that channels these comments towards other fora where they can be discussed for what they are, namely the ideas that lay people have of GMOs and their applications. It is probable that there is something of value, at least for the sake of risk communication and risk management to be learned from these comments, however naive they may look at first sight. In any case, it is a waste of resources to solicit comments that will be most likely ignored or quickly dismissed.

To this it must be added that the competent authority is always in a position to reply to comments, even when they are technically pertinent, by stating that the objections raised have been appropriately taken into consideration in the

process of risk assessment, and there is no way for the public to verify whether this actually has occurred, since there exists no formal requirement to explain how comments have been taken into consideration. In fact, to the objections of possible dispersal into the environment of Florigene Moonlight, COGEM answered that the question had already been raised and no relevant risk had been identified.

The most structured and, arguably, most compelling arguments seem to be those originating not from the lay-public, but from associations that can recruit scientists with the competence to assess the reports. Looking at the various SNIF published by *Gmoinfo*, comments written by lay people have decreased in number and, instead, emanate from specialised actors (mainly NGO's) that attempt to enter into dialogue with the other institutional actors (Consiglio dei Diritti Genetici, 2005). Within the time limit of thirty days laid down by the regulation, the public should find the means and resources to challenge the opinions of the competent authority and the claims of the applicant company, considering also the limited information published on the summary notification (due, for example, to the protection of sensitive information and commercial secrecy), and this requires both expertise and resources to fund that expertise. The *Gmoinfo* forum has been progressively colonised by specialised non-profit organisations, whose aim is to facilitate public participation, and to overcome the obstacles to people's engagement with questions relating to GMO's, namely the difficulty in collecting the necessary information from the various European Institutions involved (DG Environment, DG SANCO; EFSA etc.), in translating the technicalities of the official documents into a language widely accessible, and to voice potential citizen dissatisfaction about the ways in which the institutionalised spaces for participation are managed. These organisations have the self-appointed role of defending the interests of citizens and giving them guarantees against the political misuses of science.

However, even with the assistance of scientists outside the institutional framework, meaningful participation is a hard task. The reports published by these NGO's on this notification (see, for example, the Consiglio dei Diritti Genetici, 2005) highlight the limits of scientific work that can be performed on a summary notification that lacks some important technical details, including a bibliography. In other words, summary reports are too technical to be accessible to lay people, and not detailed enough to allow for a sound scientific appraisal by independent scientists.

Once we look into specific practices of public participation we see that EC legislation requires participation, but its indeterminacy makes it rather impracticable or ineffective, and it seems legitimate to ask whether it is worth our while to accept and collect comments from the public if we do not know what to do with them. The alleged debate between experts and the public has, in

fact, a structure that is not dialogical at all. In an equal dialogue all the debating parts should have a right to an equal contribution (in terms of time limits and number of contributions), so as to institutionalise the opportunities for "discursive challenge" (Warren, 1996: 5). But this is not the case in the above described 'due consideration' approach. The public comment process tends to be a mere formality to comply with a legal requirement, and it is in fact a one way communication from the public to the authorities, which have no obligation to reply. The decreasing number of comments sent to the *Gmoinfo* website suggests a declining interest from the part of citizens, or even a sense that effective interaction with the institutions remains very limited.

Data on access to the website shows that, when a new report is published, there is a peak of visitors, which indicates that the initiative contributes to public information. Access to data, mailing lists and e-mail pages where NGO's can communicate both with the institutions and with the public have certainly contributed positively to keeping people informed and promoting openness in the decision making process. Information is indeed a very important aspect of participation (Hanna, 2000).

But beyond openness, transparency and accountability what does participation contribute to? Proponents of lay participation hold that, at least in the case of environmental regulation, lay people can contribute to risk assessment by recounting their experiences (for example, as people who live next to a nuclear plant would) that are precluded from experts (Wynne, 1987). However, most empirical studies in support of this thesis take into consideration 'collaborative dialogue' among stakeholders and authorities in questions of local environmental policy (Connick and Innes, 2003; Fisher, 2002). Other studies on deliberation are not so optimistic about participation. From a strictly epistemic perspective broadening participation, improving public information, or even allowing a pluralism of methodologies to be employed by rival experts is not in fact effective, as it produces more indeterminate outcomes than solutions offered. Accordingly, a more inclusive risk assessment process is no more robust than that of a closed process (Rothstein, 2004). Moreover, one of the most insistent claims of supporters of deliberative democracy (or at least of some accounts of it) is that public participation leads to better policy outcomes not because it improves the substance of decision making, but rather because it makes people more motivated to accept those outcomes, or at least to attenuate dissent (Fishkin, 2005). Via public participation people are put in a position enabling them to express their opinions, and to listen to the concerns of others, hopefully also to see the reasons that inform the decision process. In other words also the justification claim can be reduced to the legitimation claim.

Yet, the suggestion that the participatory practices discussed in this paper confer legitimation to the decision-making process is far from obvious. The

frustration generated by the under-specified requirement of 'due consideration' and the creation of an appearance of consensus in situations in which divergences of opinion remains, can foster disaffection with the institution rather than enhance allegiance. An obvious expression of people's lack of trust in the possibility to influence the system from within is that in Europe protests about GMOs have reverted to the streets or other non-institutional settings. Public participants give their epistemic contributions only in forms that bypass the technical and legal frameworks set within the procedures for risk assessment, such as NGO's WebPages and open letters to the competent authorities, but also in protest movements and demonstrative action, such as the destruction of GMO test sites that attract media attention and have remarkable societal impact.

6. Conclusions

Citizen scrutiny is supposed to bring about better governance, and a greater participation in public policy decisions is usually regarded as a sign of good and dynamic democracy. In this paper, I have explained how participation is thought of as a means of to conferring *legitimacy* to public institutions, but also of providing a better epistemic *justification* to decision making outcomes. However, when we look at particular practices we understand that organising effective participation is, in reality, extremely difficult. Even more difficult is achieving the goal of improved justification and enhanced legitimation under the same institutional settings. To be sure, participation is no magic wand that can solve, at once, the problem of a democratic deficit, and ensure better science. In fact, the opposite can often occur: in some cases participation can increase institutional inefficiency, generate frustration and mistrust, and even anger among the public, or simply waste precious public resources.

Two case studies do not allow for generalisations, but can be useful as a probe of what happens to our democratic ideals once they are put into operation at an institutional level. The observed participatory practices are not appropriate to overcome the problem of power asymmetry among the various stakeholders, as the case of MON 863 illustrated. Taking the challenge of more inclusive decision making seriously requires targeting the structural inequalities of actors. This would require, for example, finding a viable solution to the problem of commercial secrecy, but also a larger investment of resources so that NGO experts can compete on an equal footing with those of the industry. And in order to democratically justify such expenditure of public money we would need better reasons than simply broadening participation *per se*. In fact, supporters of democratic practices would argue that it can be expected that de-

cision making would also improve.

However, once we separate the epistemic aspects from the democratic claim that people alone should decide (self-governance), it is difficult to make the case that technical agencies need lay participation in order to work at their best. It was shown that lay people cannot actually take part in the scientific decision making, but rather they would need experts who defend their interests versus experts who are biased towards others' interests. But then why should we subsidise (whether directly or indirectly) NGO experts to perform such a task? I think that we all agree that impartially defending the interests of all citizens is what we expect from government appointed experts.

In the field of novel biotechnologies, participation is more meaningful at a more general level, where people have to decide on the general principle guiding their (public) attitude towards GM products, the methods and procedures for their assessment. Generally people are for or against a particular application of biotechnology (e.g. genetically modified food or medical applications), rather than *pro* or *contra* the authorisation of a specific product. These general views about biotechnologies can find more adequate expression at the political level where values, principles and lines of action (rather than scientific technicalities) are discussed.

Early stage stakeholders' involvement at the time of the definition of Community initiatives, as required, for example, by the SANCO *scoping papers*, is a promising initiative in this respect. These are thought of as documents containing all the relevant information for discussion, launch and development of a Commission initiative (e.g. guidelines, legislation, expenditure of public funds) before it is submitted for approval; they are designed to find a clearer focus on the objectives to be achieved with a particular initiative, and on the policy options available. At this stage it is more likely that consumer associations and NGO's can make meaningful contributions by discussing the possible economic, environmental and social impact of the proposed initiatives and their policy alternatives.

In conclusion, the equation that more participation equals more democracy does not hold. In order to find an institutional place for our democratic ideals we need to look closer at alternative practices available, and find criteria to establish their relative merits. In this direction, I believe, supporters of deliberative democracy still have much work to do and much insight to give to policy.

Bibliography

Beck, U. 1999. *World Risk Society*. Cambridge: Polity.

Benhabib, S. 1996. *Democracy and Difference: Contesting the Boundaries of the Political*. Princeton, NJ: Princeton University Press.

Bernauer, T. 2003. *Genes, Trade and Regulation: The Seeds of Conflict in Food Biotechnology*, Princeton: Princeton University Press.

Connick, S. & Innes, J. 2003. "Outcomes of collaborative water policy making: applying complexity thinking to evaluation", *Journal of Environmental Planning and Management*, 46(2): 177-197.

Consiglio dei Diritti Genetici. 2005. *Analisi delle osservazioni del pubblico alle notifiche presentate secondo la direttiva 2001/18/CE*, Rome.

D'Agostino, F. 1996. *Free public reason: making it up as we go.* New York: Oxford University Press.

Elster, J. 1998. *Deliberation and Constitution Making, in Deliberative Democracy.* Cambridge: Cambridge University Press: 97-122.

Falke, J. 2002. "Institutionen zur Risikobewertung und zum Risikomanagement im In- und Ausland: Analyse der vorhandenen Konzepte, Umsetzung und Erfahrungen über den Aufbau solcher Institutionen sowie daraus zu ziehende Schlussfolgerungen", Studie im Auftrag der Ad-hoc-Kommission. *„Neuordung der Verfahren und Strukturen zur Risikobewertung und Standardsetzung im gesundheitlichen Umweltschutz der Bundesrepublik Deutschland"*.

FAO/WHO. 1996. *Expert Consultation on Biotechnology and Food Safety Report.* Rome (http://www.fao.org/es/ESN/food/pdf/biotechnology.pdf). Accessed on 3.11.2005.

Ferretti, M.P. 2006. "Participatory strategies in the regulation of GMO products in the EU", in J. Steffek, et al. (eds.) *Civil Society Participation in International and European Governance: A Cure for Its Democratic Deficit?* Houndmills: Palgrave Macmillan (forthcoming).

Fiorino, D. J. 1989. "Technical and Democratic Values", *Risk Analysis*, vol. 9, no. 3: 293-299.

Fisher, F. 2002. *Citizens, Experts, and the Environment: The Politics of Local Knowledge Durham*, NC: Duke University Press.

Fishkin, J. 1991. *Democracy and Deliberation. New Directions for Democratic Reform*, Yale University Press.

Giddens, A. 1998. *The Third Way. The Renewal of Social Democracy*, Cambridge: Cambridge University Press.

Gutmann, A. and Thompson, D. 1996. *Democracy and Disagreement: Why Moral Conflict Cannot Be Avoided in Politics, and What Sshould Be Done About It*. Cambridge:The Belknap Press of Harvard University Press.

Habermas, J. 1990. *Moral Consciousness and Communicative Action*, Cambridge, MA: MIT Press.

Hanna, K.S. 2000. "The paradox of participation and the hidden role of information: a case study", *Journal of the American Planning Association*, 66(4): 398-410.

Hansson, O.S. 1996. "Decision Making Under Great Uncertainty", *Philosophy of the Social Sciences* 26: 369-386.

Hood, C. Rothstein, H.; Baldwin, R. 2003. *The Government of Risk. Understanding Risk Regulation Regimes.* New York: Oxford University Press.

Hunold, C. and Young, I. 1990. "Justice, Democracy ad Hazardous Siting", *Political Studies* 46:82-95.

James, P., Kemper, J., Pascal, G. 1999. *A European Food and Public Health Authority. The future of scientific advice in the EU*, December, 1999. (http://europa.eu.int/comm/food/fs/sc/future_food_en.pdf). Accessed on 29.09.2005.

Jasanoff, S. 1987. "Contested Boundaries in Policy-Relevant Science", Social Studies of Science, 17:195-230.

Kates, R.W. and Kasperson J.X. 1983. "Comparative risk analysis of technological hazards (a review)"., *Proceedings of the National Academy of Sciences USA,* 80: 7027-38.

Lafond, F. 2001. *The Creation of the European Food Authority*. European Issuers N.10. (http://www.notre-europe.asso.fr/IMG/pdf/Probl10-en.pdf). Accessed on 25.01.2006.

Lash, S. 2000. "Risk Culture". In *The Risk Society and Beyond. Critical Issues for Social Theory*, edited by B. Adam, Beck, U., Van Loon, J. London: Sage.

Levison, S.C. 1992. "Activity Types and Language", in P. Drew and J.Heritage (eds.) *Talk at work: Interaction in Institutional Settings*, Cambridge University Press: 66-100.

Lowarance, W. 1976. *Of Acceptable Risk: Science and the Determination of Safety*, Los Altos, Calif.: Kaufmann.

Lucas, P. 2002. "Valuing Birds in the Bush: For Pluralism in Environmental Risk Assessment", *Environmental Values*, 11, 2: 177-191.

Majone, G. 1989. *Evidence, Argument and Persuasion in the Policy Process*. New Haven: Yale University Press.

McGarity, T.O. 1990. Public Participation in Risk Regulation, *RISK: Health, Safety & Environment* (*http://www.piercelaw.edu/Risk/Vol1/spring/McGarity.htm*). Accessed on 29.09.2005.

Medina Ortega, M., 1997. *Report (A4-0020/97) on alleged contraventions or maladministration in the implementation of Community law in relation to BSE, without prejudice to the jurisdiction of the Community and national courts* (Medina Report), EU Temporary committee of inquiry into BSE, 7 Feb. 1997.

Millstone, E.; Brunner, E.; Mayer, S. 1999. "Beyond Substantial Equivalence", 401 *Nature* (http://www.greenpeace.org.br/transgenicos/pdf/beyond_substantial_equivalence.pdf#search=%22Beyond%20Substantial%20Equivalence%22). Accessed on 29.09.2005.

Munton, R. 2003. "Deliberative democracy and environmental decision-making", in *Negotiating environmental change: new perspectives from social science*, edited by L. M. a. S. I. Berkhout F. Cheltenham: Edward Elgar.

Perhac, R. M., Jr. 1998. "Comparative Risk Assessment: Where does the Public fit in?", *Science, Technology, & Human Values*, vol. 23, no. 2, pp. 221-241.

Rothstein, H. 2004. "Precautionary Bans or Sacrificial Lambs? Participative Risk Regulation and the Reform of the UK Food Safety Regime", *Public Administration*. 82 (4): 857-881.

Seralini, G. 2005. *Report on MON 863 GM maize produced by MONSANTO Company June 2005 .Controversial effects on health reported after subchronic toxicity test : a confidential rat 90 day feeding study* (http://www.greenpeace.de/fileadmin/gpd/user_upload/themen/gentechnik/bewertung_monsanto_studie_mon863_seralini.pdf). Accessed on 15.01.2006.

Shrader-Frechette, K. S. 1991. *Risk and Rationality: Philosophical Foundations for Populist Reforms.* Berkeley: University of California Press.

Simmons, A. 1999. "Justification and Legitimacy", *Ethics* 109: 739-771.

Slovic, P. 2003. "Going Beyond the Red Book: The Sociopolitics of Risk", *Human and Ecological Risk Assessment*, 9(5): 1-10.

Taylor, C. 1985. "Legitimation Crisis?", In *Philosophy and the Human Sciences:Philosophical Papers 2*. Cambridge: Cambridge University Press.

Thompson, Paul, B. and Dean Wesley, R. 1996. "Competing Conceptions of Risk", *Risk: Health Safety and the Environment* 7: 361-84.

Vogel, D. 2001. *The New Politics of Risk Regulation in Europe*, London: LSE.

Warren, M.E. 1996. "Deliberative Democracy and Authority", *American Political Science Review*, 90, 1: 46-60.

Wynne, B. 1987. *Risk Management and Hazardous Waste*, New York: Springer Verlag.

Wynne, B. and Irwin, A. 1996. "Introduction": in Wynne, B. E. and Irwin, A. (eds.), *Misunderstanding science? The public Reconstruction of Science and Technology*, Cambridge: Cambridge University Press, 1996, 1-17.

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